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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,682	08/03/2001	Leslie Magnus	5801-D1-01-CA	8305

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/921,682

Applicant(s)

Magnus et al.

Examiner

Phyllis Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on May 21, 2002

2a) ☒ This action is **FINAL** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-5 is/are pending in the application.

4a) If the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-5 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) file on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6) ☐ Other:

Art Unit: 1614

Applicants' Amendment filed May 21, 2002, Paper No. 5, is acknowledged. Claims 1-5 remain under consideration.

A Terminal Disclaimer filed May 21, 2002, Paper No. 7, is further acknowledged.

An Information Disclosure Statement filed May 31, 2002, Paper No. 8, is further acknowledged and has been reviewed.

Claim 1 was rejected in the last Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,306,910. Following the submission of a Terminal Disclaimer, the rejection of record is withdrawn.

Claims 1-5 were rejected in the last Office Action as being unpatentable over Ehrenberg et al., Neurology. It was asserted Ehrenberg teaches the administration of gabapentin, a GABA analog of instant Formula I, to treat a mammal suffering from a disorder of sleep.

Applicants argue periodic limb movement disorder may result in insomnia, but does not necessarily result in insomnia. Applicants urge secondary insomnias are preferably treated by treating the underlying cause of the insomnia rather than by treating the insomnia symptom.

Applicants' arguments have been given careful consideration but are not found persuasive. Although treating the primary cause of insomnia may be preferable, instant claim 1 does not distinguish primary from secondary insomnia. Accordingly, the rejection of record is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1614

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Pande, A. C., U.S.

Patent No. 5,510,381.

Pande teaches the administration of compounds of instant Formula I to enhance delta-wave (deep) sleep. Enhancement of delta-wave sleep would have reasonably provided a treatment for insomnia. See column 2, lines 21-22, as well as lines 35-55. Further, see column 3, lines 24-25, where an oral dosage of 20 to 200 mg is disclosed, within the range required by claims 4 and 5.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al., Journal of Neural Transmission(abstract).

Rao teaches the administration of gabapentin, a compound of instant Formula I, to increase sleep stages 3 and 4 through an increase in the bioavailability of serotonin. An increase in sleep stages 3 and 4 would have reasonably provided a treatment for insomnia.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1614

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

August 1, 2002

*Phyllis Spivack*

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**